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Sun Pharma Will Take Concert's Alopecia Drug The Rest Of The Way

by Joseph Haas

Coming up after Lilly's Olumiant and Pfizer's ritlecitinib in alopecia areata, deuterated ruxolitinib is said to offer a differentiated profile including patient-reported outcomes data.

Concert Pharmaceuticals, Inc. placed all of its hope on a deuterated formulation of ruxolitinib in alopecia areata, offloading other programs to bet on deuruxolitinib that it would offer a better safety and efficacy profile than *Eli Lilly and Company*'s approved JAK inhibitor Olumiant (baricitinib). But with cash dwindling, the US biotech is under agreement for sale to India's *Sun Pharmaceutical Industries Ltd.*, which said it wants the drug as an addition to its dermatology portfolio.

The two companies announced on 19 January that they have tentatively agreed to a tender offer of $8 per share for all outstanding stock in Concert – a 33% premium over the Lexington, MA-based firm's 30-day average trading price – valuing the deal at $576m. In addition, Sun included a pair of contingent value rights (CVRs) tied to commercial performance of deuruxolitinib (CTP-543) in alopecia areata. The CVR would pay Concert shareholders $1 per share upon the first commercial sale of deuruxolitinib in the US no later than 31 March 2027, as well as an additional $2.50 per share if the product yields net sales of $500m or more over any period of four consecutive quarters by 31 December 2029.

Sun said it is building a global franchise of dermatology and ophthalmology products and that deuruxolitinib would contribute a potentially best-in-class drug to that effort. It currently markets drugs in more than 100 countries globally.

Lilly obtained the first US Food and Drug Administration approval in AA last June for Olumiant, a JAK1/2 inhibitor already approved to treat rheumatoid arthritis and COVID-19. (Also see "*Lilly's Olumiant Is First Drug FDA Approved For Alopecia Areata*" - Scrip, 13 Jun, 2022.) The Indianapolis

pharma reported global sales of $625m for Olumiant through the first three quarters of 2022, including $105m in the US. The product surpassed the blockbuster threshold in 2021 with nearly $1.12bn in global sales.

Pfizer Inc. is next in line for approval in AA – an autoimmune disorder that causes patchy baldness – with its investigational JAK3/TEC inhibitor ritlecitinib under FDA review with an action date this June. But Concert has asserted that deuruxolitinib, a deuterated formulation of ruxolitinib (Lilly/*Incyte Corporation*'s Jakafi), can offer differentiation in the JAK inhibitor class with a better safety profile, strong efficacy, quick onset of action and validation via a patient-reported outcome measured in Phase III, the Satisfaction of Hair Patient Reported Outcome (SPRO). (Also see "*Concert's Patient-Reported Outcome Could Help Differentiate Its Alopecia Therapy*" - Scrip, 1 Aug, 2022.)

PRO May Offer Differentiation In Class

The FDA recommended that Concert include a patient-reported outcome in its pivotal trials in AA. In the Phase III THRIVE-AA2 study, which reported data last August, at 24 weeks of treatment, 47% of patients receiving an 8mg twice-daily dose and 52% of those getting a 12mg twice-daily dose reported being either "satisfied" or "very satisfied" with their results. Those are the two highest scores possible on the five-part scale for SPRO, Concert noted. The drug also hit the SPRO endpoint in the earlier Phase III study, THRIVE-AA1, with both studies also meeting the primary endpoint of Severity of Alopecia Tool (SALT) score. (Also see "*Concert's CTP-543 Shows Advantages Over Lilly, Pfizer Candidates For Alopecia*" - Scrip, 23 May, 2022.)

With success in both pivotal studies, Concert told investors it planned to file deuruxolitinib for approval in AA during the first half of 2023, but also said its cash likely would run out this year. Sun Pharma plans to fulfill Concert's plan of filing a new drug application on that timeline, and argued that its global infrastructure can provide broad access to the product in the US and elsewhere. Concert also planned to file deuruxolitinib for approval in the EU and had initiated open-label, long-term extension studies to back filings in both the US and Europe.

Sun, which had cash totaling $1.6bn at the end of Q3 2023, said it will pay for Concert with cash. Concert's board of directors unanimously voted in favor of the tender offer, but Sun still must get a majority of the biotech's outstanding shares to close the transaction.

Analysts commenting on the deal offered differing assessments, with Truist Securities' Joon Lee saying deuruxolitinib's commercial potential might attract a competing offer for Concert. In a same-day note, Lee projected $333m in US net sales in 2027 and $512m in 2029, making the CVR payment achievable for Concert. He added that the increase in Concert's share price during the day on 19 January might indicate anticipation of a competing bid for the company. The stock finished the trading day up 20% to $8.29 per share, compared with a closing price of $6.90 on 18 January.

JMP Securities analyst Jason Butler, however, said in a 19 January note that he does not expect a competing bid for Concert, even though he models revenue for deuruxolitinib that could trigger payment of the first commercial milestone in 2026 and the second in 2029. He called Sun “a solid strategic fit” for Concert, noting that it has an established US commercial presence in dermatology, ranking second in prescriptions in that sector.

Concert decided to offload the rest of its pipeline of deuterated compounds, focused on neuropsychiatric indications, in March 2022 to *Terran Biosciences, Inc.* at undisclosed terms and focus on obtaining approval of deuruxolitinib in AA. (Also see "*Deal Watch: AbbVie Partners With Gedeon Richter In Neuropsychiatry*" - Scrip, 18 Mar, 2022.) Privately held Terran does not provide any pipeline information on its website, so the status of those candidates is not known publicly; the New York-based company also acquired a pair of Phase III central nervous system candidates from *Sanofi* last April as well as *Blumentech S.L.*’s intellectual property portfolio for psychedelic therapeutics. (Also see "*Cryptic Terran Licences Advanced CNS Assets From Sanofi*" - Scrip, 22 Apr, 2022.)